K122972

510(k) Summary

OCT 24 2012

CDC Zirconia Blanks

1. **Date of Summary Preparation:** September 18, 2012

2. **Submitting Firm:** Continental Dental Laboratory

3. **Contact Person:**

Jerry Doviack, CDT
President
Continental Dental Laboratory
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4. **Name of Medical Device**

Proprietary Name: CDC Zirconia Blanks

Regulation Name: Porcelain Powder for Clinical Use
Regulation Number: 872.6660
Product Code: EIH
Classification Name: Powder, Porcelain
Classification: Class II

5. **Predicate Device:** K093560, Upcera Zirconia Blanks
Shenyang Upcera Company, Ltd.

6. **Description of Medical Device:**

CDC Zirconia blanks are pressed and sintered blocks of Yttria stabilized Zirconia for use in CAD/CAM milling machines. After the Zirconia block is milled, it is sintered into a high strength all ceramic material suitable for copings, inlays, onlays, crowns, and bridges.

6. **Intended Use**

CDC Zirconia Blanks are intended for use with CAD/CAM technology to produce all-ceramic dental restorations (copings, frameworks, inlays, onlays, crowns and bridges) as prescribed by a dentist.

7. **Safety & Effectiveness**

The successful prior use of the components of CDC Zirconia Blanks product in legally marketed devices, the similarity of the formulations used in this device and earlier devices, and the

substantially equivalence of CDC Zirconia Blanks to prior cleared devices support the safety and effectiveness of the CDC Zirconia blank product for the intended use.

It has been shown in this 510(k) submission that the difference between CDC Zirconia Blanks and the predicate device do not raise any questions regarding its safety and effectiveness.

END OF SECTION

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Continental Dental Ceramics, Incorporated
Mr. Jerry Doviack, CDT
President
1873 Western Way
Torrance, California 90501

OCT 24 2012

Re: K122972
Trade/Device Name: CDC Zirconia Blanks
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: II
Product Code: EIH
Dated: September 18, 2012
Received: September 26, 2012

Dear Mr. Doviack:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (If known): K122972

Device Name: CDC Zirconia Blanks

Range of Indications:

CDC Zirconia Blanks are intended for use with CAD/CAM technology to produce all-ceramic dental restorations (copings, frameworks, inlays, onlays, crowns and bridges) as prescribed by a dentist.

This product is for professional use only. Not for use by the general public or OTC.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K122972